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XYMOGEN, INC.

**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF UTAH, CENTRAL DIVISION**

THORNE RESEARCH, INC. and SOFTGEL FORMULATORS, INC., Plaintiffs, vs. XYMOGEN, Inc. Defendant.	Case No. 2:13-CV-784 TS Judge Ted Stewart Magistrate Judge Paul M. Warner XYMOGEN'S MOTION FOR LEAVE TO AMEND OR SUPPLEMENT INVALIDITY CONTENTIONS
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I. INTRODUCTION

Defendant XYMOGEN, Inc. (“XYMOGEN”) hereby seeks leave to amend or supplement its Preliminary Invalidity Contentions for U.S. Patent No. 8,491,888 (“the ’888 patent”). New evidence supporting invalidity of the ’888 patent obtained through discovery, confirmed by the Court’s recent claim construction of the term “non-crystalline,” have significantly expanded the scope of Xymogen’s defenses and counterclaims. This is information that XYMOGEN did not know, and could not have known, last November, when the deadline for final invalidity contentions came. In light of this, and as explained further below, good cause exists to permit XYMOGEN to amend its contentions. Further, Plaintiffs Thorne Research, Inc. and Softgel Formulators, Inc. (together, “Plaintiffs”) will not be prejudiced by permitting XYMOGEN to amend its contentions. Therefore, XYMOGEN’s motion for leave to amend or supplement should be granted.

II. PROCEDURAL HISTORY

This action commenced when Plaintiffs filed their complaint against XYMOGEN on August 22, 2013, alleging infringement of the ’888 patent. (Dkt. 2). Xymogen filed its answer and counterclaim on January 16, 2014. (Dkt. 11). On February 6, 2014, Plaintiffs filed their reply to Xymogen’s counterclaims. (Dkt. 16).

Soon thereafter, the parties’ counsel met and conferred, and the parties jointly submitted their Attorneys’ Planning Report and Proposed Scheduling Order on March 11, 2014. (Dkt. 17). On the basis of that Planning Report and Proposed Scheduling Order, on March 12, 2014,

Magistrate Judge Furse entered the Scheduling Order currently governing this case. (Dkt. 19).

By subsequent stipulation, the fact discovery cut-off was set for June 12, 2015. (*See* Dkt. 28).¹

Under the Scheduling Order, the Final Infringement Contentions were due August 14, 2014; the Final Unenforceability and Invalidity Contentions were due August 28, 2014; and the Final Non-Infringement Contentions were due September 11, 2014. (*Id.* at 3). Certain deadlines set out in the Scheduling Order were modified, based on joint motions by the parties. (*See* Dkt. Nos. 21-22 and 27-28). The deadline for the Final Unenforceability and Invalidity Contentions was extended to September 12, 2014, and ultimately to November 26, 2014. (Dkt. 27). In accordance with the Scheduling Order, XYMOGEN served its preliminary invalidity contentions on June 9, 2014. (*See* Declaration of Scott Oliver, submitted herewith, at ¶ 3). However, XYMOGEN did not serve final invalidity contentions because, at the time the final invalidity contentions were due, it formed the belief that no amendments from the preliminary invalidity contentions were necessary. (Oliver Decl., ¶ 5).

Evidence that came to light through depositions taken by Xymogen in January and February 2015 – *after* the current deadline for Xymogen to serve its final invalidity contentions had passed – proved that the '888 patent may be invalid. Specifically, deposition testimony provided in January and February 2015 revealed information that: (a) put into question the true inventors of the '888 patent under 35 U.S.C. §102(f); (b) suggested the '888 patent may be

¹ Plaintiffs have also moved to de-designate certain documents produced by XYMOGEN, which XYMOGEN designated as privileged. (Dkt. 110). XYMOGEN opposed that motion on November 20, 2015. (Dkt. 119). The parties agreed that Plaintiffs would have until January 8, 2016 to file a reply. (Dkt. 121, 122). The parties have also stipulated to an extension of deadlines for motions for summary judgment to ten days after the Court rules on Plaintiffs' pending motion on de-designation. (Dkt. 114).

invalid under the on-sale bar set out in 35 U.S.C. §102(b), and (c) indicated there was a deliberate violation of the best mode requirement under 35 U.S.C. §112(a). (Dkt. 40 at 2).

The Court handed down its *Markman* order on October 8, 2015. (Dkt. 106). The Court construed “non-crystalline” as “no CoQ10 crystals are visible by light microscope at magnifications of 640X,” and “carrier oil” as “an oil that carries CoQ10 molecules across the absorption cells in the intestine, increases the volume of the dose, and increases the overall surface area from which the CoQ10 can be absorbed.” (Dkt. 106 at 6, 9). This confirmed XYMOGEN’s theories of invalidity developed through discovery in the early part of 2015.

The parties have since met and conferred to attempt to reach an agreement as to amendment of the parties’ contentions. (Oliver Decl., at ¶ 6). These attempts have proved unsuccessful. (*Id.* at ¶ 7).

III. LEGAL STANDARD

Utah Local Patent Rule 3.4 provides, “a party may amend its ... Final Non-infringement, or Unenforceability and Invalidity Contentions only by order of the court upon a showing of good cause and absence of unfair prejudice to opposing parties, made no later than fourteen (14) days of the discovery of the basis for the amendment....”

The good cause inquiry first considers whether the moving party has been diligent in moving to amend, and then considers the prejudice to the accused infringer should the motion be granted. *See O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1367-68 (Fed. Cir. 2006).

IV. ARGUMENT

A. XYMOGEN Has Been Diligent in Moving to Amend

Good cause exists for the Court to grant XYMOGEN leave to amend for two reasons.

First, XYMOGEN has been diligent in developing its invalidity case, including through discovery and through the *Markman* process. *Second*, XYMOGEN has diligently sought to meet and confer with Plaintiffs on the possibility of one or both parties stipulating to the amendment of their respective contentions following the entry of the Court's *Markman* order in October 2015.

1) XYMOGEN Diligently Developed Its Invalidity Case Through Discovery

XYMOGEN diligently pursued its case through discovery from November 2014 through to the close of fact discovery in June 2015. As outlined in XYMOGEN'S motion to amend the scheduling order (Dkt. 40), new theories of invalidity only came to light during the depositions of Messrs. Trevor Jones and Robin Koon on January 21 and February 12, 2015, respectively. In particular, Mr. Jones's testimony suggested – for the first time – that the '888 patent is likely invalid because the named inventors were not, in fact, the first inventors of the claimed subject matter of the '888 patent. While XYMOGEN had suspected that this was true from the outset, and while the true inventor had testified about his invention, Jones was the first corroborating witness on these facts. (Dkt. 40 at 3-4; Exh. A (Jones Dep. Tr. at 7:1-21; 15:6-17:20 and 23:3-24:6)). Mr. Koon's testimony likewise suggested – for the first time – that a CoQ10 formulation that embodies at least some of the claims of the '888 patent was shipped to a third-party entity in the U.S. in 2002-2003. (Dkt. 40 at 4-5; Exh. B (Koon Dep. Tr. at 104:18-108:5; 117:15-17); Exh. C (Steele Dep. Tr. at 103:5-104:20)). Mr. Koon also testified that a crucial step in making a

crystal-free CoQ10 product was known by Mr. Steele and Mr. Koon, but that the pair made the deliberate decision to omit that information from the '888 patent application, in violation of the best mode requirement under pre-AIA 35 U.S.C. § 112. (Dkt. 40 at 5-6; Exh. B (Koon Dep. Tr. at 160:20-162:5). XYMOGEN was diligent in developing these theories of invalidity through additional depositions that were noticed for March and April 2015. (Oliver Decl., at ¶ 3).

Numerous district courts have granted motions for leave to amend invalidity contentions, where new theories or proofs of invalidity only emerge during discovery. *See, e.g., Oleksy v. General Elec. Co.*, 2013 WL 3944174, *2-*5 (N.D. Ill. 2013) (granting accused infringer leave to amend invalidity contentions to add a prior use anticipation defense, the court concluding that the accused infringer did not learn of the prior use until a deposition during the course of litigation, and therefore its delay in bringing motion to amend did not show a lack of diligence); *Prism Technologies, LLC v. AT & T Mobility, LLC*, 2014 WL 656794, *1-*2 (D. Neb. 2014) (granting motion to supplement invalidity contentions to add new prior art that was only obtained through discovery, and was not available from a traditional prior art search); *Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories Ltd.*, 2013 WL 3336859, *4-*6 (D.N.J. 2013) (granting accused infringer leave to amend its invalidity contentions to add new contentions regarding a previously pleaded on-sale bar defense and to add a new improper inventorship defense following receipt of plaintiff's document production during discovery).

In addition, the theories of invalidity that XYMOGEN first identified in early 2015 depended on the Court's construction of the term "non-crystalline" in October 2015. Under the Court's construction, "non-crystalline" means "no CoQ10 crystals are visible by light microscope at magnifications of 640X." (Dkt. 106 at 4). This construction went against

XYMOGEN's proposal, that "non-crystalline" should mean "lacking crystals." (*Id.*) Numerous district courts have granted leave to amend invalidity contentions where the court issues a claim construction order that does not adopt the movant's proposed construction. For example, in *Celgene Corp. v. Natco Pharma Ltd.*, the district court affirmed the magistrate's order permitting accused infringer to amend its invalidity contentions and add defenses under 35 U.S.C. § 112, where the amendment was sought 23 days after the court had issued its claim construction order adopting the plaintiff's proposed construction for a particular claim term. 2015 WL 4138982, *3-*5 (D.N.J. 2015). The district court judge in that case held that the applicable local patent rule was broad enough to apply in cases where the court adopted a claim construction position that was different from the movant's position. *Id.* Similarly, in *Radware Ltd. v. F5 Networks, Inc.*, the court granted leave to amend invalidity contentions based on court's claim construction, allowing the accused infringer to add a new § 112 defense and supplemental claim charts based on previously disclosed prior art references. 2014 WL 3728482, *3 (N.D. Cal. 2014). *See also Ferring B.V. v. Watson Laboratories, Inc.*, 2013 WL 2325111, *2 (D. Nev. 2013) (granting accused infringer leave to amend its invalidity contention due to the court's claim construction order); *and see* LPR 3.4 ("An example of a circumstance that may support a finding of good cause, absent undue prejudice to the non-moving party, includes a claim construction by the court different from that proposed by the party seeking amendment.")

Indeed, in this case, the Court's construction has – for the first time – confirmed XYMOGEN's invalidity theories. That is, the CoQ10 formulation that was shipped in 2002-2003 may not have been "non-crystalline" under XYMOGEN's proposal, but does satisfy the Court's construction, and therefore it falls within the terms of the on-sale bar under 35 U.S.C.

§102(b). Similarly, the step that was deliberately omitted from the '888 patent application dealt with a method for making crystal-free CoQ10 that falls within the Court's construction of "non-crystalline," and therefore, the failure to disclose this crucial step confirms the violation of the best mode requirement under 35 U.S.C. § 112 and therefor limits the remedies available to the Plaintiffs. Therefore, in accordance with the guidance of the case law, leave to amend should be granted, and XYMOGEN should be permitted to amend or supplement its invalidity contentions.

2) XYMOGEN Has Been Diligent in Its Meet and Confer Efforts

XYMOGEN acknowledges that more than 14 days have passed since the Court's *Markman* order. However, XYMOGEN submits that this delay is due to attempts to obtain a stipulation rather than bring another motion before the Court. After the Court entered its *Markman* order, XYMOGEN has sought to meet and confer with Plaintiffs to seek a stipulation on the amendment of the invalidity contentions. (*See* Oliver Decl., at ¶ 6). A stipulation could have avoided the need for the present motion. *See West v. Jewelry Innovations, Inc.*, 2009 WL 152136, *2–*4 (N.D. Cal. 2009) (parties' stipulation to permit reciprocal amendments of preliminary infringement and invalidity contentions provide good cause of the accused infringer to amend its invalidity contentions) (citing *Atmel Corp. v. Authentec, Inc.*, 2008 WL 276392, at *3 (N.D. Cal. Jan. 31, 2008)).

However, a stipulation was not forthcoming. XYMOGEN received Plaintiffs' final answer on this issue, refusing to stipulate to allow XYMOGEN to amend its contentions, on December 14, 2015. (*See* Oliver Decl., at ¶ 7). Under these circumstances, a flexible approach in determining whether to grant leave to amend should be adopted. *See, e.g., United Therapeutics Corp. v. Sandoz, Inc.*, 2013 WL 7902649, *5–*6 (D.N.J. 2013) (granting leave to

amend invalidity contentions, the court holding that the timing of bringing the motion to amend – three months after the discovery of additional prior art – was “not offensive, given the host of considerations that re-shaping an invalidity case might invoke.”) Indeed, significant periods of delay have been excused, where the accused infringer has otherwise demonstrated diligence in preparing its case. For example, in *Motio, Inc. v. Avnet, Inc.*, the court granted the accused infringer leave to amend its invalidity contentions even though there had been delay in discovering the prior art system, and 17 months had passed since the court had issued its claim construction order. 2015 WL 5952530, *2-*5 (E.D. Tex. 2015). The court found that the reference was not well-known and could have “paramount” importance to the case, and that therefore, patentee could not argue that the reference was unimportant.

The same is true here: the information discovered through the deposition testimony of Messrs. Jones and Koon was not known to XYMOGEN until January and February 2015, and was developed through further depositions noticed for March and April 2015 -- well after the deadline to serve the final invalidity contentions had passed. This testimony is of paramount importance to XYMOGEN’s case; indeed, any *one* of these theories could *on its own* support a finding of invalidity of the ’888 patent. But the viability of these defenses was not known until the Court entered its *Markman* order on October 8, and XYMOGEN then sought a stipulation from Plaintiffs to an amendment of its invalidity contentions (and Plaintiffs’ infringement contentions) in light of this ruling. Under these circumstances, XYMOGEN was diligent in pursuing its theories of invalidity, and any perceived delay in bringing the present motion should be excused.

B. Plaintiffs Will Not Be Unduly Prejudiced by the Proposed Amendment

Plaintiffs will not be unduly prejudiced by allowing XYMOGEN to amend or supplement its contentions. Plaintiffs have had notice of XYMOGEN's potential new theories of invalidity since at least March 2015, when XYMOGEN moved to amend the scheduling order. (Dkt. 40). Further, as of the date of the instant motion, expert discovery has not yet begun, the trial date has not been set, and motions for summary judgment have not yet been briefed. There can be no undue prejudice to Plaintiffs in these circumstances. *See, e.g., Celgene*, 2015 WL 4138982 at *3-*5 (finding no adverse prejudice resulted from allowing amendment because expert reports had not yet been exchanged, fact discovery could be reopened for the limited purpose of conducting discovery on the new invalidity contentions, a trial date had not been set, and additional expenses in amending responses to invalidity contentions did not constitute undue prejudice); *Lexar Media, Inc. v. Pretec Electronics Corp.*, 2007 WL 1170633, *1 (N.D. Cal. 2007) (granting accused infringer's motion to amend its invalidity contentions on the basis that there is no prejudice where the patentee was on notice of the possible defenses during the claim construction briefing and the patentee failed to show how it would have conducted discovery differently if the new invalidity allegations had been in the case earlier). Indeed, given evidence that Plaintiffs continue to seek, it is highly likely that Plaintiffs will at some point seek to amend their infringement contentions. That they will not stipulate now is presumably an attempt to gain some tactical advantage.

V. CONCLUSION

The purpose of the parties' respective contentions is to prevent unfair surprise--to lay each party's cards on the table about their respective infringement and invalidity theories, so that

summary judgment can be orderly, and trial is predictable. XYMOGEN is confident in its invalidity theories and plans to present them to the Court at summary judgment. Under these circumstances--and in light of the Court's recent Markman ruling and evidence discovered after the original deadline had passed, good cause exists to allow XYMOGEN to amend its invalidity contentions, and no prejudice will result to Plaintiffs. XYMOGEN respectfully requests that this motion for leave be granted.

Dated: December 31, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of December, 2015, I electronically filed the foregoing **XYMOGEN'S MOTION FOR LEAVE TO AMEND OR SUPPLEMENT INVALIDITY CONTENTIONS** with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to the following counsel of record:

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